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| 10/549,820 | 09/20/2005 | Norbert Heske | 289-PDD-03-09 US | 3682 |
| 79990 7590 08/03/2009 | | | | |
| C. R. Bard, Inc. Bard Peripheral Vascular, Inc. 1415 W. 3rd Street P.O. Box 1740 Tempe, AZ 85280-1740 | | | | |
| EXAMINER | | | | |
| STOUT, MICHAEL C | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/549,820

Applicant(s)

HESKE ET AL.

Examiner

MICHAEL C. STOUT

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 5-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 10 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

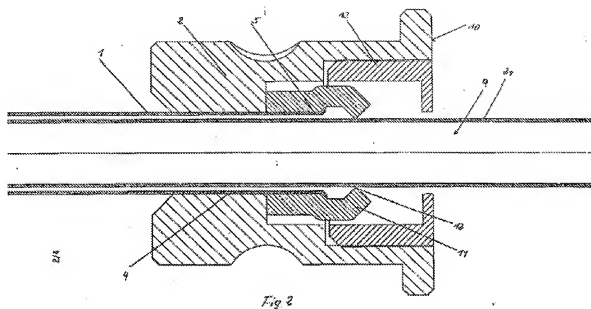
This detailed action is in regards to United States Patent Application 10/549,820 filed on 5/1/2009 and is a first action based on the merits of the application.

Claim Rejections - 35 USC § 112

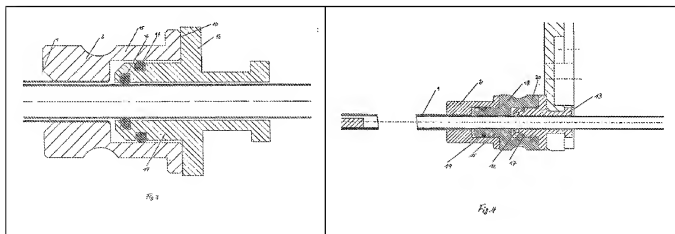
The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 is drawn to the species shown in Figures 1 and 2.



Claim 1 recites the limitation of sealing element being "positioned on the proximal end of the coaxial cannula" which is drawn to the species shown in Figure 2 above. Claims 3 and 4 are drawn to alternative species shown in Figures 3 and 4, wherein the sealing element is positioned on different elements.



Claims 3 and 4 are drawn to a combination of embodiments which are not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Ishida (US 6,221,050 B1).

Ishida teaches a biopsy apparatus, comprising:

a coaxial cannula (2) for use in tissue, the coaxial cannula having an interior wall (See Figures 1 and 2);

a biopsy needle unit (4) configured for insertion into the coaxial cannula (see Figure 2), the biopsy needle unit having an exterior wall (See Figure 2), and when inserted into the coaxial cannula an intermediate space is formed between the interior wall of the coaxial cannula and the exterior wall of the biopsy needle unit (see Figure 1);
and

an elastic member defining a sealing lip (the sealing member has a lip which engages the inner needle 7), the sealing lip having a single edge (inner surface of the seal shown in Figure 7), the sealing element being mounted to the coaxial cannula (Figure 2), with a gap being formed between the single edge of the sealing lip and the biopsy needle unit (when the needle is in the sealing element there is a gap between the inner surfaces outer edge and the needle outer wall similar to what is shown in Figure 8), and wherein the elasticity of the sealing lip is such that, given an underpressure in the intermediate space between the exterior wall of the biopsy needle unit and the interior wall of the coaxial cannula, the single edge of the sealing lip comes into contact with the biopsy needle unit to form a seal against the biopsy needle unit (the sealing element is configured such that given an underpressure in the intermediate space the inner surface will be drawn against the needle and provides a seal against the needle unit), see at least columns 8, Lines 13-65.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldenberg (US 6,033,369 B1).

Regarding claim 1, Goldenberg teaches a biopsy apparatus, comprising: a coaxial cannula (14) configured for insertion in tissue with the aid of a mandrel (mandrel 60), the coaxial cannula having a proximal end and an interior wall (see Figures 1 and 2): are a biopsy needle unit configured for insertion into the coaxial cannula after the mandrel is removed from the coaxial cannula (inner cannula 16 which is capable of

being inserted into the cannula after the mandrel has been removed), the biopsy needle unit having an exterior wall (see Figure 2), an interior with specimen removal space (interior lumen of the cannula 16) and a longitudinally movable specimen separating device (the inner cannula 16 has a snare 20 for separating tissue), see Column 2, Line 56 through Column 3, Line 67.

Goldenberg fails to disclose a sealing element on the proximal end of the coaxial cannula.

Brannon teaches a sealing element positioned on the proximal end of the coaxial cannula (16 positioned on 10, see Figure 2), the sealing element being configured to enclose an intermediate space between the interior wall of the coaxial cannula and the exterior wall of the biopsy needle unit (the sealing element being capable of enclosing an interior space), wherein the sealing element the is configured to provide an the air outlet of the intermediate space when the biopsy needle unit is inserted into the coaxial cannula (the sealing element is capable of of providing an air outlet during insertion of a biopsy needle, especially until the solid outer edge forms an air tight seal with the sealing element) and is configured to prevent air from entering the intermediate space after the needle unit has been positioned and a vacuum has been created in the interior space of the biopsy needle (the seal provides a seal capable to maintain a vacuum applied to suction port 18).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the device taught by Goldenberg to include a sealing

element as taught by Brannon in order to provide a seal to enable a vacuum source to evacuate fluid from the fluid collecting reservoir, see abstract.

Regarding claim 10, Goldenberg teaches the biopsy apparatus of claim 1, wherein the longitudinally movable specimen separating device is a cutting sleeve having the exterior wall (the inner member 16, share 20 have a sharpened or pointed inner surface/edge, see Column 3, Lines 1-20).

Allowable Subject Matter

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Contact Info

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL C. STOUT whose telephone number is (571)270-5045. The examiner can normally be reached on M-F 7:30-5:00 Alternate (Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. C. S./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736